K010613

OCT 1 2 2001

Oceanic Medical Products, Inc.

William M. Gates
Vice President Innovation and Development
Email: mooregates@journey.com
8005 Shannon Industrial Park Road
Atchison, KS 66002
T-913 874 2000, Fax-2005

ATTACHMENT H

510(k) SUMMARY

MAGELLAN-2200 ANESTHESIA MACHINE

Submitters Name: William M. Gates

Name of Contact Person: William M. Gates

Date Summary was Prepared: February 27, 2001

Trade Name: Magella-2200 Anesthesia Machine

Common Name: Anesthesia Machine

Classification Name: Gas Machine-Anesthesia (per 21 C.F.R. section 868.5160)

Summary: The Magellan-2200 is substantially equivalent to the Drager Narcomed-M (K97425) and Cardinal Medical Specialties' OBA-1(K000859) anesthesia machines.

The Magellan-2200 is a compact anesthesia machine containing all of the basic features that are normally found on such devices. It has been designed to be used in military field hospitals, hospital operating rooms, outpatient surgical centers and in office-based anesthesia as well as in veterinary clinics.

The Magellan-2200 has been designed to withstand shipping and other movement rigors and remain intact without component breakage.

The Magellan-2200 has been designed to be easy to use with all of the working components in full view of the operator. The Magellan-2200 was designed to be operator friendly to the user.

The Magellan-2200 has been designed to allow for ease-of maintenance for technical staff.

The Magellan-2200 contains all of the individual features and components normally found on basic anesthesia machine platforms, with the same principles of operation and substantially equivalent technological characteristics to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 2 2001

Mr. William M. Gates
Oceanic Medical Products, Inc.
8005 Shannon Industrial Park Lane
Atchison, KS 66002

Re: K010613
Magellan-2200 Anesthesia Machine, Model 1
Regulation Number: 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: Class II (two)
Product Code: 73 BSZ
Dated: October 3, 2001
Received: October 4, 2001

Dear Mr. Gates:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

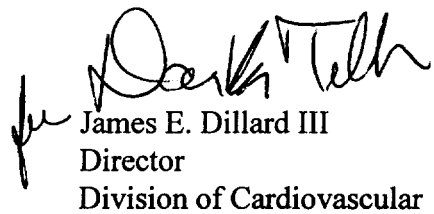
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Oceanic Medical Products, Inc.

510(k) Number: K010613

Device Name: Magellan-2200, Model 1, Anesthesia Machine

Indications for Use:

The Magellan-2200, Model 1 Anesthesia Machine may be used for spontaneous, manually assisted or automatic ventilation of patients during anesthesia. It may be used for the delivery of gases and anesthetic vapor.

The Magellan-2200, Model 1 Anesthesia Machine is capable of monitor/alarm functions for oxygen concentration, breathing pressure and respiratory volumes.

Prescription Use? ✓ yes

Division of Cardiovascular & Respiratory Devices
510(k) Number K010613